



PATENT

Attorney Docket No. F-5366

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

BOGGS, ET AL.

Serial No.: 09/111,915

Filed: July 8, 1998

Examiner: Richard W. Ward

Art Unit: 1723

For: COMPOSITE MEMBRANE WITH
PARTICULATE MATTER SUBSTANTIALLY
IMMOBILIZED THEREIN

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NAME Andrew G. Kolomayets

SIGNATURE *Andrew G. Kolomayets*

Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF DR. SHMUEL STERNBERG

I, Shmuel Sternberg, declare as follows:

1. I am a named co-inventor of the invention claimed in the above-identified patent application and an employee of Baxter Healthcare Corporation. Baxter Healthcare Corporation is a subsidiary of Baxter International Inc., the owner of the above-identified patent application.

2. I earned a Bachelor of Science Degree in Chemical Engineering in 1962 from Georgia Tech University and a Master of Science Degree in Chemical Engineering in 1964 from Carnegie (now

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Carnegie-Mellon) University. In 1968, I earned a PhD in Polymer Science and Engineering from Case-Western Reserve University.

3. I have been an employee of Baxter Healthcare Corporation since 1990, in the Corporate Research and Technical Services Division, where I hold the title of Baxter Distinguished Scientist. Much of my work at Baxter has been in the research and development of filtration membranes for medical uses. Prior to my employment with Baxter, I was employed by Memtek between 1983 and 1990, where I held the position of Vice-President of Research and Development. Memtek manufactures filters and filtration apparatus, including membranes, and I was intimately involved in the development of membranes. Prior to my employment with Memtek, I was employed by the Millipore Corporation between 1976 and 1981, where I held the title of Manager of Research. Millipore is one of the leading manufacturers of membranes, filters and filtration apparatus and, as at Memtek, I was intimately involved in the development of membranes at Millipore. Prior to my employment with Millipore, I worked for Abcor (later Koch Membrane Systems) between 1969 and 1975 where I held the title of Manager of Material Technologies. Between 1967 and 1969, I worked for Amicon Corporation where I held the title of Senior Research Engineer. In addition, I am a named inventor and/or co-inventor on eleven (11) United States Patents, mostly in the field of membranes and filtration apparatus.

4. The present application discloses and claims a flexible, composite sheet membrane. The membrane, in one example, is made from a polymer and a particulate dispersed within the polymer. In this example, the blended polymer solution and particulate are coated on both sides of a polymeric sheet or support to form the membrane. The membrane has a porous, outer skin over the membrane interior. We have observed that less of the particulate is present near the area of the outer skin than is present further into the interior of the membrane. As more of the particles are located further into the interior of the membrane, and away from the outer skin, it is less likely that these particles may become dislodged from the membrane and enter any fluid that contacts the membrane. This is particularly desirable if the membrane is to be used with biological or medical fluids that may be administered to a human subject.

5. It is our understanding that the reason for this non-uniform distribution of particles across the membrane is the method by which the membrane is made. The membrane described above and claimed in the application is made by passing the polymeric support through a chamber filled with the polymeric/particulate blend. The chamber, shown in Figures 9 and 10 of the application, is generally V-shaped and includes a narrow passageway or gap at the bottom of the "V." The passageway is defined by downwardly extending walls

and has a predetermined length. As the support is passed through the chamber and the bottom passageway, the sides are coated with the polymeric/particulate blend. It is my belief that, as the support passes through the narrow passageway, shear forces are generated between the walls of the passageway and the support. The shear forces urge the particles within the blend further into interior of the membrane and away from the area near the outer skin.

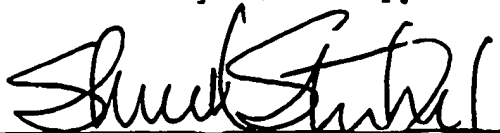
6. I have read and am familiar with U.S. Patent 4,728,432 to Sugiyama et al. Sugiyama et al. describe a porous membrane that is made from an absorbent in the form of a powder or fine particles fixed on a support such as a polyethylene sheet (Col. 5, line 8). According to Sugiyama et al., the membrane can be prepared "by the known method of producing porous membranes" including taking a polymer solution containing the absorbent dispersed therein and applying to the support "by means of flowcasting, dipping, coating, or spraying" (Col. 3, lines 29-45). Sugiyama et al., however, do not describe any specific apparatus for applying the polymer blend onto the support.

7. I am very familiar with the membrane-forming techniques of flowcasting, dipping, coating and spraying from my many years of experience in the field of membranes. None of these techniques

would inherently create the shear forces that I believe are created in our method of making the membrane of the present application. Using the techniques of flowcasting, dipping, coating or spraying would not, by necessity, result in a membrane with a particle distribution as described and claimed in the present application. In fact, I am familiar with methods of casting, dipping and coating membranes that would not generate shear forces of the type generated in our method and, therefore, would, in all likelihood, not result in a membrane with the particle distribution described and claimed in the present application. Without knowing more about the specifics of the methods and the apparatus (which are not disclosed or suggested by Sugiyama et al.), I would not assume and, in my opinion, a person of skill in the field would not assume that the techniques described in Sugiyama et al. would result in a membrane having the particle distribution described and claimed in our patent application. Accordingly, Sugiyama et al. does not expressly or inherently disclose a membrane in which less of the particulate is disposed near the outer skin than further into the interior of the membrane, nor would such a membrane be obvious from the techniques identified in the Sugiyama, et al patent.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements

were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC 1001 and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.



Dr. Shmuel Sternberg

May 7, 2001

Date